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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,898	10/03/2001	Zhiyuan Gong	1781-0163P	5940
2292	7590	12/18/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,898	Applicant(s) GONG ET AL.	
	Examiner Joseph T. Voitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a 371 national stage filing of PCT/SG99/00079, filed July 16, 1999 which claims benefit to foreign application 9900811-2, filed February 18, 1999 in Singapore.

Examiner's comment

As indicated in the office action mailed Applicants amendment filed May 12, 2003, paper number 12, was been received and entered. Claims 1-18 were canceled and claims 19-59 were entered. Claims 19-59 were pending.

Presently, Applicant's amendment filed September 2, 2003, has been received and entered. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 19-21 have been renumbered 60-62.

Claims 19-62 are pending. In addition, the amendments proposed for claims 1-18 have not been entered because these claims have been canceled. Further, it is noted that some of the proposed claim amendments include dependency on the proposed canceled claims (for example claim 7 would depend on claims 1, 2, 3, or 4). Applicants election of Group VII, claims 7-13 and

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16, is noted. However, these claims do not exist and newly added claims directed to the subject matter are not pending.

Appropriate correction is required. It is suggested that non-elected claims 19-62 be canceled, and that claims directed to Applicants' elected invention be added. It is noted that any new claim set should start number at claim 63.

Election/Restriction

Applicants' response to the restriction requirement is noted. However, as discussed above, the amendment filed on May 12, 2003, paper number 12, canceling all claims drawn to the inventions set forth in the restriction requirement and presenting only claims drawn to a new invention is **non-responsive** (MPEP § 821.03). As acknowledged previously by Applicants, the claims 19-59 are not readable on the elected invention. Claims 60-62 are dependent on canceled claim 10 and thus, not drawn to the elected invention.

Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

The original restriction requirement is re-iterated below for Applicants' convenience.

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 5, 6, 14, 15, drawn to a zebrafish cytokeratin gene promoter, classified in class 536, subclass 24.1.
- II. Claims 2, 5, 6, 14, 15, drawn to a zebrafish creatine kinase gene promoter, classified in class 536, subclass 24.1.
- III. Claims 3, 5, 6, 14, 15, drawn to a zebrafish fast muscle isoform of myosin light chain 2 gene promoter, classified in class 536, subclass 24.1.
- IV. Claims 4, 5, 6, 14, 15, drawn to a zebrafish ribosomal protein P0 gene promoter, classified in class 536, subclass 24.1.
- V. Claims 7-13, 16, drawn a transgenic fish comprising a zebrafish cytokeratin gene promoter, classified in class 800, subclass 20.
- VI. Claims 7-13, 16, drawn a transgenic fish comprising a zebrafish creatine kinase gene promoter, classified in class 200, subclass 20.
- VII. Claims 7-13, 16, drawn a transgenic fish comprising a zebrafish fast muscle isoform of myosin light chain 2 gene promoter, classified in class 800, subclass 20.

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VIII. Claims 7-13, 16, drawn a transgenic fish comprising a zebrafish ribosomal protein P0 gene promoter, classified in class 800, subclass 20.

IX. Claim 17, drawn a transgenic fish comprising a zebrafish ribosomal protein P0 gene promoter, classified in class 800, subclass 20.

X. Claim 18, drawn a transgenic fish comprising a zebrafish ribosomal protein P0 gene promoter, classified in class 800, subclass 20.

Claims 5, 6, 14, 15 are generic to groups I-IV and will be examined to the extent they encompass the elected invention. Claims 7-13, 16 are generic to groups V-VIII and will be examined to the extent they encompass the elected invention.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.

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3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In the instant case, Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

Specifically, the inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different polynucleotide sequences represent unique and different promoter sequences with different inherent properties as demonstrated by a particular expression pattern in a cell.

Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case each of the transgenic fish comprise a different promoter which results in a material different genome in the transgenic fish. Additional, the inherent activity of each of the promoters if expressed may provide a unique phenotype to each of the transgenic fish of each of the inventions.

Inventions I-IV and V-VIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the promoters can be used for expression studies in vitro, as probes for detecting the presence of the respective gene, or as a target sequence for an anti-sense oligonucleotide.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods require a transgenic fish comprising different promoters. The genome of the transgenic fish in each case are different and unique thus the methods require different starting materials. Further, the methods require the administration and analysis of two different classes of compounds; steroid-like compounds and heavy metals.

Inventions V-VIII and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods require a transgenic fish comprising promoters which are different from those specifically set forth in the inventions of groups V-VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for each one of Group I-X is not required or coextensive with each other, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

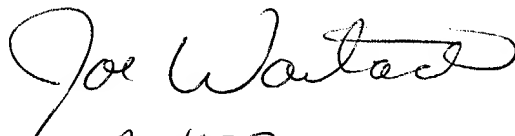
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


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